

Pelvic Prolapse Repair Procedures Involving Graft or Prosthesis

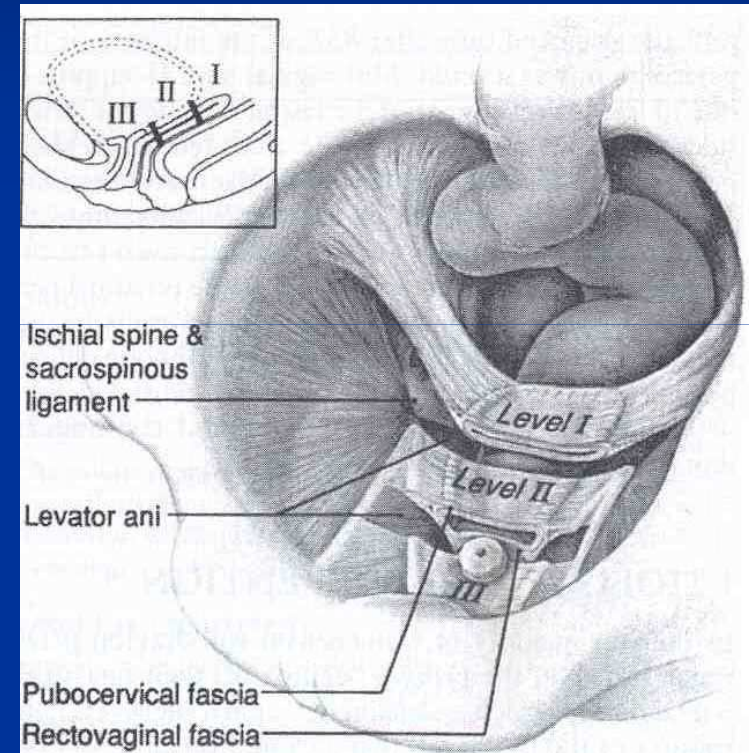
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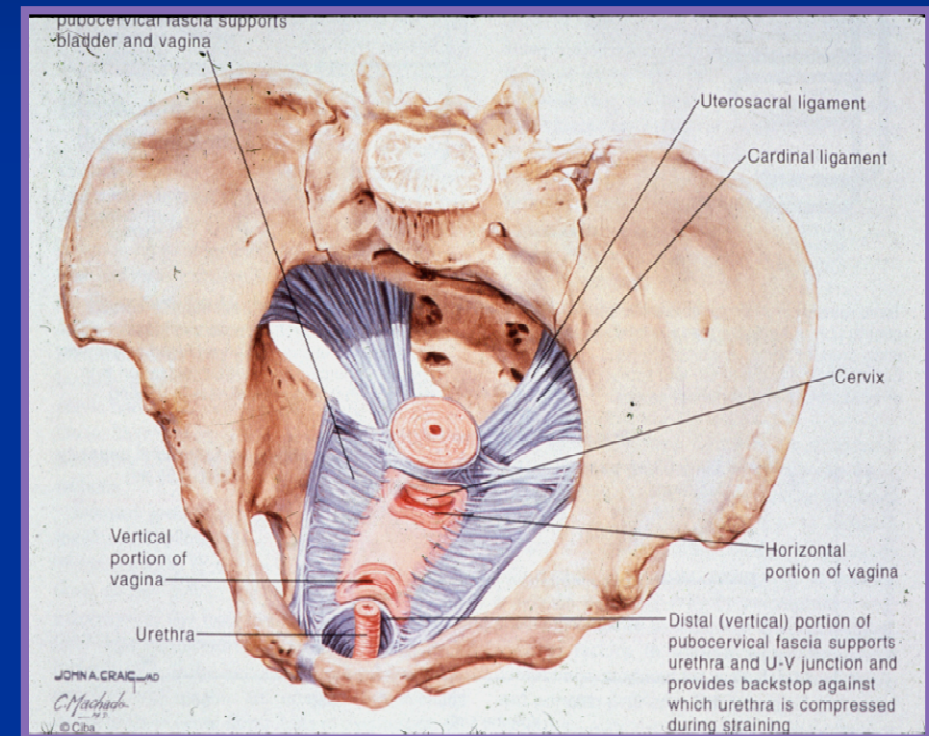
Pelvic Prolapse Repair Procedures Involving Graft or Prosthesis

- Various Grafts and Prosthesis, including synthetic, allogenic, xenogenic, or autologous materials, have all received 510K clearance from the FDA
- A surgical approach for pelvic prolapse repair procedures that are compensatory in nature, specifically, these procedures use some type of graft or prosthesis, to replace and support deficient native vaginal wall and pelvic tissues.



Conventional Surgery for Pelvic Prolapse Repair

- Restorative Surgical Procedures
 - Uses patient's own endogenous or native support structures
- For Example:
 - Anterior Repair
 - Anterior Colporrhaphy/Kelly Plication
 - High recurrence rate (29% to 40%)
 - Posterior Repair
 - Levator myorrhaphy
 - Associated with high dyspareunia rates
- Apical
 - Iliococcygeus suspension
 - Not ideal for large prolapse



Indications

Prolapse Repair Procedures that Involve a Graft or Prosthetic Implant

- Any appropriate patient with symptomatic anterior, posterior, or apical prolapse of grade 2 or greater

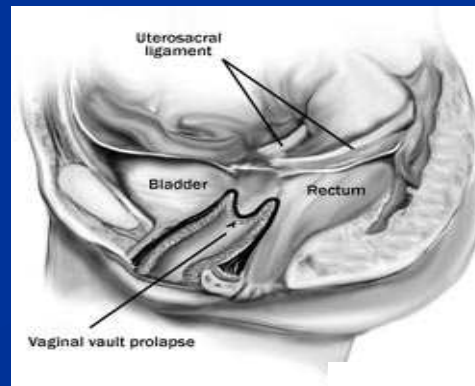
Anterior Prolapse

Herniation of the bladder in the anterior vaginal wall



Apical Prolapse

Upper portion of the apex descends in the vaginal canal

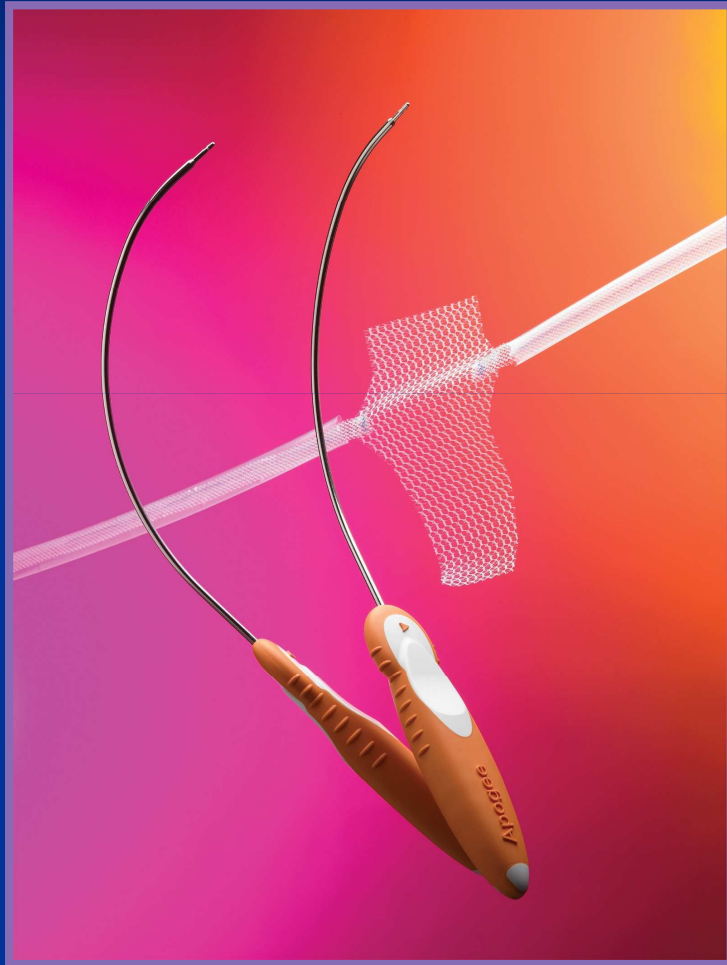


Posterior Prolapse

Herniation of the rectum in the posterior vaginal wall



Prolapse Repair Procedures: Examples of Graft or Prosthetic Implants



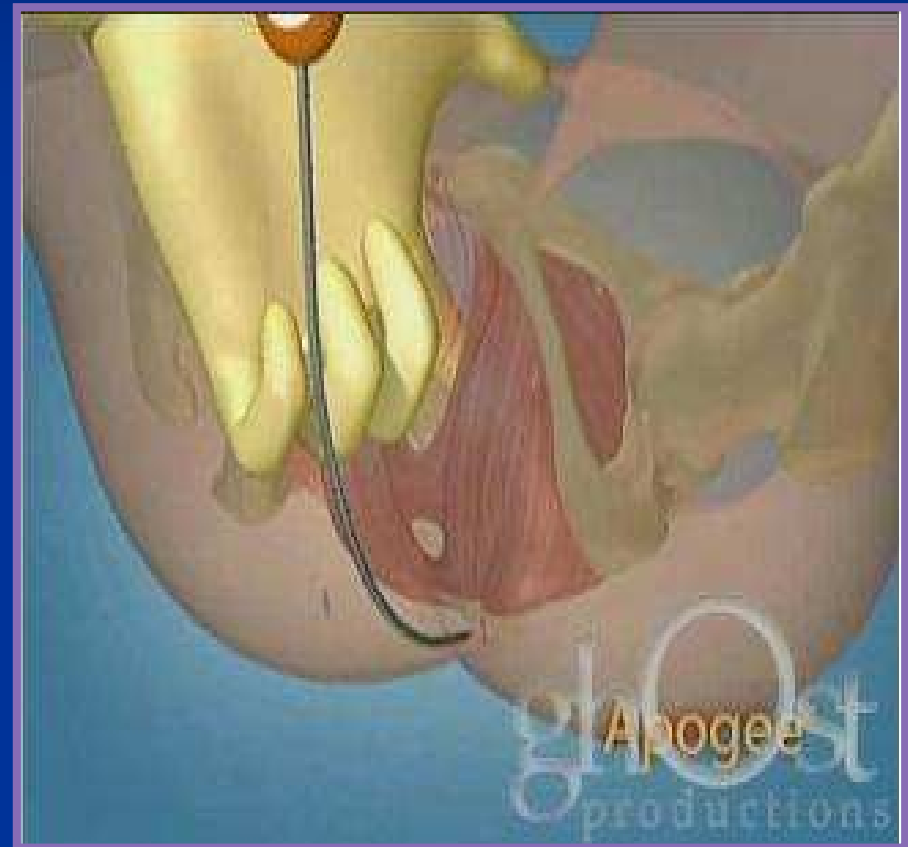
Apical & Posterior Repair



Anterior Repair

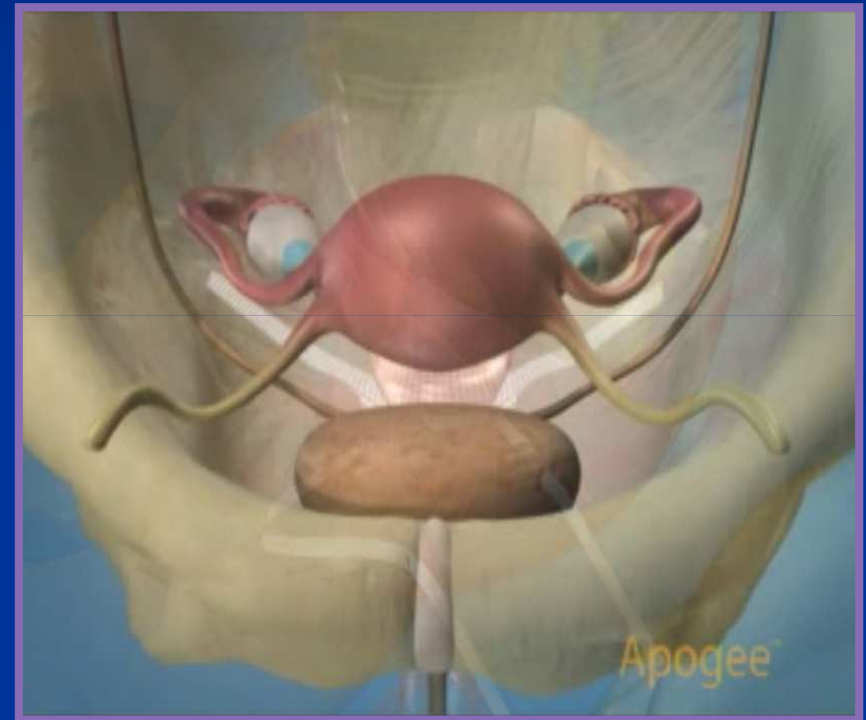
Apical and Posterior Prolapse – Procedural Steps

- Midline incision is made in posterior vaginal wall
- Vaginal mucosa is dissected up to ischial spines
- Two curved needles are inserted through buttock in the ischiorectal fossa, exiting in the posterior vaginal wall



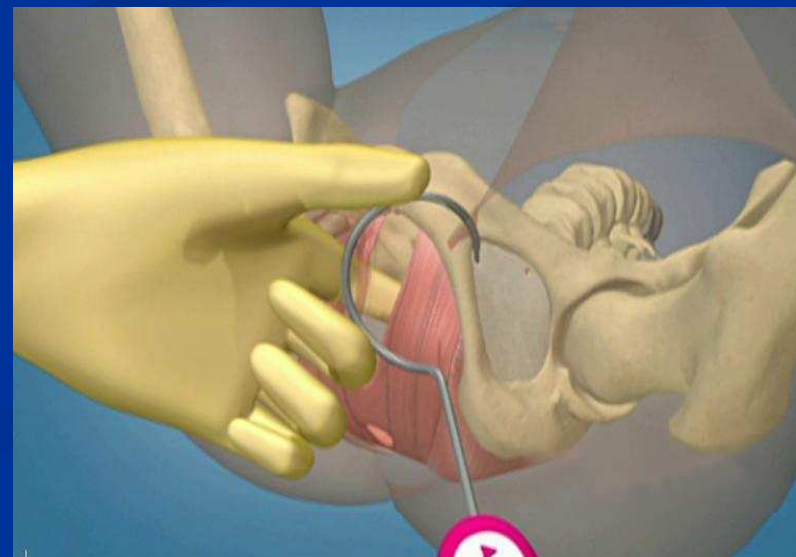
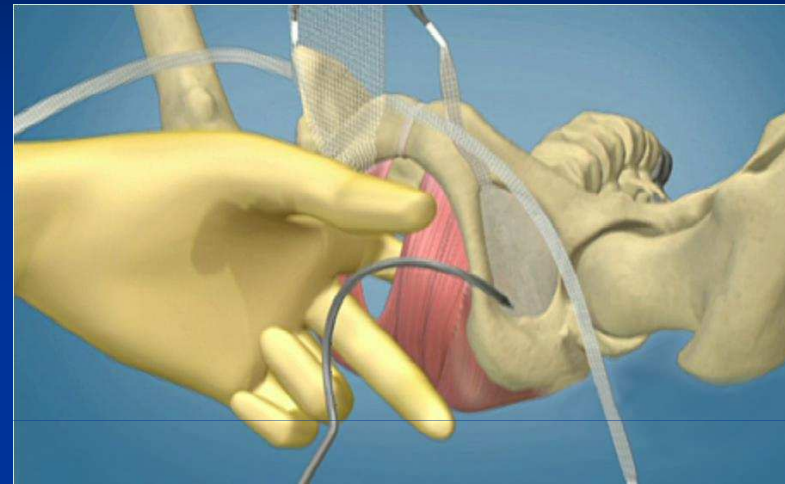
Apical and Posterior Prolapse – Procedural Steps

- Graft connector is attached to the respective needle, and the needle is withdrawn through the skin incision
- Graft is fixated at the apex and trimmed appropriately
- Final graft tensioning is made
- Arm graft is trimmed at the level of the skin incision
- Skin and vaginal incisions are closed



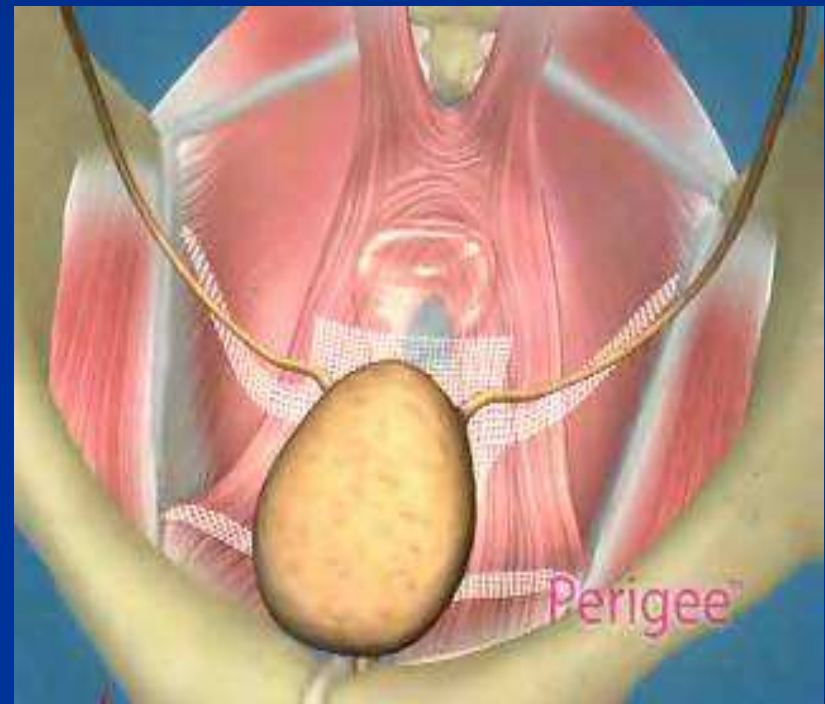
Anterior Prolapse – Procedural Steps

- Midline incision made in anterior vaginal wall
- Vaginal mucosa is dissected up to apex
- Two helical needles are inserted through obturator foramen on patients right and left side, exiting through vaginal incision
- Two more needles are inserted through obturator foramen inferior to helical needles, exiting through vaginal incision towards apex

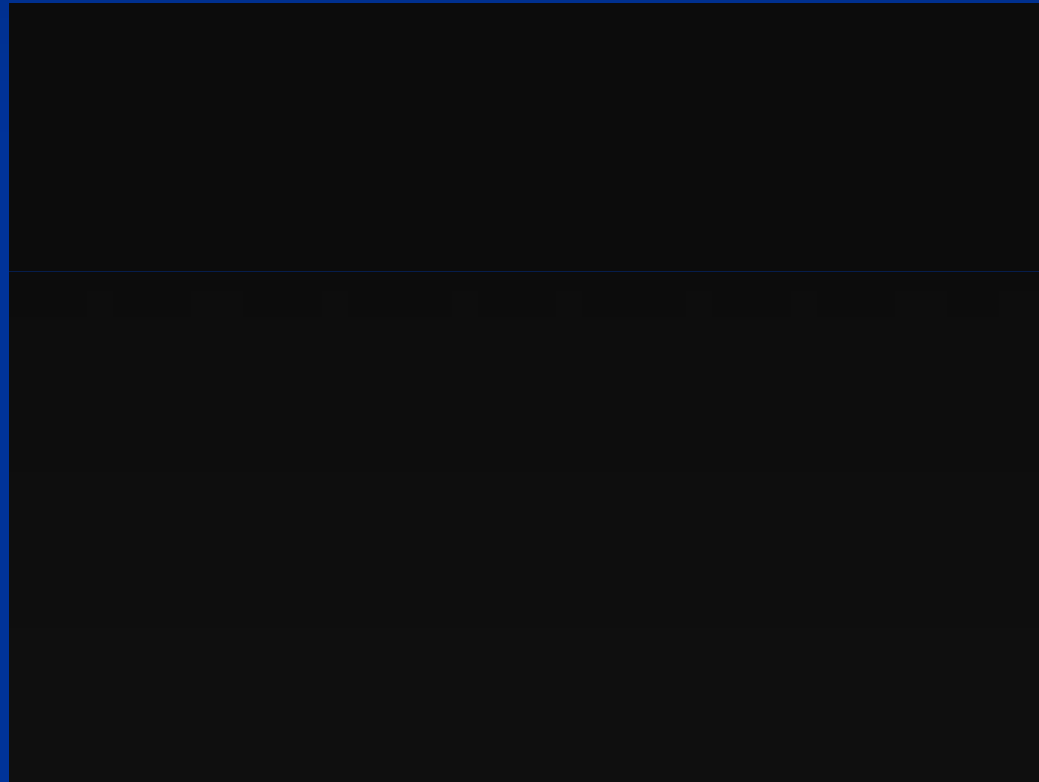


Anterior Prolapse – Procedural Steps

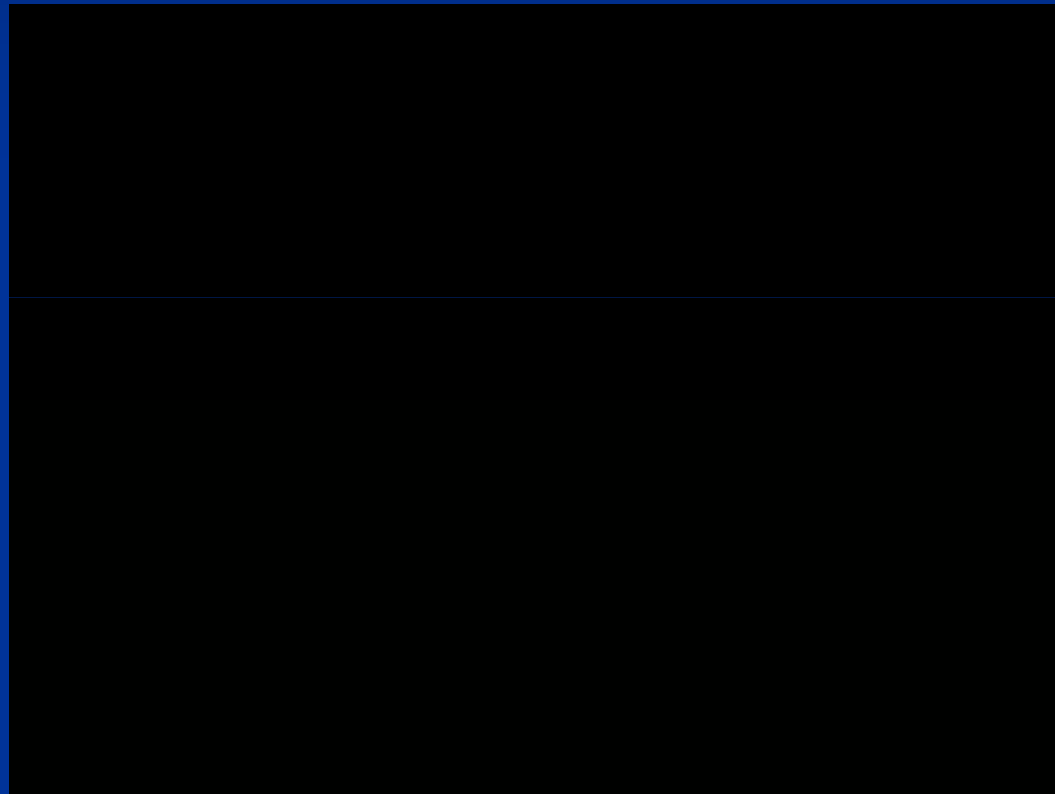
- Graft connector is attached to the respective needle, and the needle is withdrawn through the skin incision
- Graft is positioned to lay flat underneath the bladder
- Final Graft tensioning is made
- The arm Graft is trimmed at the level of the skin incision
- Skin and vaginal incisions are closed



Apical & Posterior Repair Video Clip



Anterior Repair Video Clip



Key Documentation Points

- Procedure performed in operating room
- Anterior, Posterior, or vaginal fixation, reconstruction, or suspension
- Use of graft or prosthesis
 - Use of “Apogee, Perigee, Prolift or Avaulta graft or prosthesis kit

Data Issues

- Lack of specific ICD-9-CM codes for pelvic prolapse repair procedures that involve graft or prosthesis has created on going data issues:
 - Inability to track procedures clearly in the encoded data
 - Hindrance of data review and analysis
 - Inability to differentiate prolapse repair procedures that use grafts or prosthesis

Questions

- Thank You